filed June 30, 1994, which issued as U.S. Patent 5,538,982 on July 23, 1996; which is a divisional of Application No. 07/946,635, filed on September 18, 1992, which issued as U.S. Patent 5,360,820 on November 1, 1994; the entire contents of which are hereby incorporated by reference and for which priority is claimed under 35 U.S.C. § 120; and this application claims priority of Application Nos. 91 20172.3; 92 02839.8; and 92 04151.6 filed in Great Britain on September 20, 1991; February 11, 1992; and February 27, 1992, respectively, under 35 U.S.C. § 119.--

REMARKS

The specification has been amended to update the status of the parent application, which is now patented.

Applicants respectfully request that an interference be declared under the provisions of 35 U.S.C. § 135 between the above-identified Application No. 09/986,679 and U.S. Patent 5,576,317 (hereinafter referred to as the Pfizer '317 patent), which issued on November 19, 1996, and is assigned to Pfizer Inc. of New York, New York.

Applicants herein present the following facts in compliance with 37 C.F.R. § 1.607. The following paragraph numbers correspond to the paragraph numbers of § 1.607(a).

(1) Applicants request an interference with U.S. Patent 5,576,317.

(2) The Proposed Counts for the interference are as follows:

PROPOSED COUNT 1

A pharmaceutical composition for the treatment or prevention of emesis comprising a $5HT_3$ receptor-antagonist, an NK-1 receptor antagonist and a pharmaceutically acceptable carrier.

OR

A method of treating or preventing emesis in a mammal, comprising administering to said mammal an anti-emetic effective amount of a pharmaceutical composition comprising a $5HT_3$ receptor antagonist, an NK-1 receptor antagonist and a pharmaceutically acceptable carrier.

OR

A method of treating or preventing emesis in a mammal, comprising administering to said mammal a $5HT_3$ receptor antagonist and an NK-1 receptor antagonist in amounts that render the combination of such two active agents effective in the treatment or prevention of such disorder.

PROPOSED COUNT 2

A pharmaceutical composition for the treatment or prevention of emesis comprising a $5HT_3$ receptor-antagonist selected from the group consisting of ondansetron, tropisetron, granisetron and metclopramide, an NK-1 receptor antagonist and a pharmaceutically acceptable carrier.

OR

A method of treating or preventing emesis in a mammal, comprising administering to said mammal an anti-emetic effective amount of a

pharmaceutical composition comprising an NK-1 receptor antagonist and either ondansetron, tropisetron, granisetron and metclopramide.

OR

A method of treating or preventing emesis in a mammal, comprising administering to said mammal a $5HT_3$ receptor antagonist selected from the group consisting of ondansetron, tropisetron, granisetron and metclopramide and an NK-1 receptor antagonist in amounts that render the combination of such two active agents effective in the treatment or prevention of such disorder.

(3) Claim 1 of the Pfizer '317 patent corresponds exactly to the first alternative of Proposed Count 1, claim 4 of the Pfizer '317 patent corresponds exactly to the second alternative of Proposed Count 1, and claim 7 of the Pfizer '317 patent corresponds exactly to the third alternative of Proposed Count 1. Claims 3, 5, 8, 9, 10, 12, 13 and 14 of the '317 patent also correspond to Proposed Count 1.

Claims 2, 6 and 11 of the '317 patent correspond to proposed Count 2.

(4) Claim 11 of the present '679 application corresponds exactly to the first alternative of Proposed Count 1. Claim 14 of the present '679 application corresponds exactly to the second alternative of Proposed Count 1. Claim 16 of the present '679 application corresponds exactly to the third alternative of Proposed Count 1.

Claims 3, 12, 15 and 19 of the '679 application correspond to Proposed Count 2.

It is to be noted that claim 1 in the present '679 application corresponds exactly to claim 18 of parent Application No. 08/706,836, which was filed on September 3, 1996. Claim 1 of the present application (and therefore claim 18 of the parent '836 application) corresponds substantially to claim 4 of the Pfizer '317 patent except that present claim 1 recites that the NK_1 antagonist is used in combination with a systemic anti-inflammatory corticosteroid or $5HT_3$ antagonist. Thus, although claim 1 of the present '679 application varies slightly in wording from claim 4 of the Pfizer '317 patent, these claims have substantial overlap and are directed to the same invention. Therefore, claim 1 of the present '679 application corresponds to Proposed Count 1.

Claim 3 of the present '679 application, claim 20 in the parent '836 application and claim 6 of the Pfizer '317 patent (which all correspond to Proposed Count 2) substantially overlap since two of the recited NK-1 receptor antagonists (i.e., ordansetron and granisetron) are identical. Therefore, these claims are directed to the same invention and correspond to Proposed Count 2.

Claims 2 and 4-10 in the present '679 application correspond exactly to claims 19 and 21-27, respectively, in the parent '836 application, the latter claims having been submitted to the USPTO on

September 3, 1996, prior to the issuance of the Pfizer '317 patent on November 19, 1996.

(5) All of the terms which appear in any application claim corresponding to Proposed Counts 1 and 2 are present in the disclosure of the '679 application and also in the parent '836 application. Appendix A, attached hereto, applies the terms of claims 1 and 3 (corresponding to Proposed Counts 1 and 2) to the disclosure in the present '679 application as well as the disclosure in the parent '836 application.

(6) Applicant submits that the claims of the present '679 application, which correspond to Proposed Counts 1 and 2, do not violate 35 U.S.C. § 135(b). 35 U.S.C. § 135(b) provides in relevant part:

> "A claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made *prior to one year* from the date on which the patent was granted . . ." *(emphasis added)*.

This provision requires an applicant to present "conflicting claims" prior to one year from the date of patent issuance.

The Pfizer '317 patent issued on November 19, 1996. The applicant herein presented claims substantially the same as the claims in the Pfizer patent in parent Application No. 08/706,836 on September 3, 1996. The applicant subsequently cancelled the "conflicting claims" from the application during *ex parte* prosecution on May 22, 1997 (after issuance

of the '317 patent). However, the original presentation of the "conflicting claims" occurred during the pendency of the Pfizer application and before the Pfizer '317 patent issued. These claims were also present in the '836 application after the Pfizer '317 patent issued. Applicant has reintroduced these previously cancelled "conflicting claims" in the present application.

Such reintroduction of claims is permitted according to the decision in *Tezuka, et al. v. Wilson, et al.*, 224 USPQ 1030 (Bd. Pat. App.s Int. 1984), which interprets the relevant statutory provision. Pursuant to *Tezuka*, Applicant is entitled to reintroduce the "conflicting claims" in the present divisional application even though the divisional application was filed on November 5, 2001, more than one year after the issuance of the Pfizer patent on November 19, 1996.

In the *Tezuka* case, the Board interpreted the words "prior to" in 35 U.S.C. § 135(b). The issue before the Board was whether Wilson had presented claims in his application for the same or substantially the same subject matter as *Tezuka*'s patent claims 1 to 3 prior to one year from the date on which the *Tezuka* patent was granted as required by 35 U.S.C. § 135(b). Wilson's parent application, filed on September 6, 1977, contained original claims 24-30, directed to a cement-forming liquid for use as a component of a poly(carboxylate) cement. These claims were cancelled on July 21, 1978, and were not reasserted in the parent application. These claims were then presented in Wilson's involved application filed on June 14, 1979, which was more than one

year after the issuance of the *Tezuka* patent on May 16, 1978. Claim 32 was also presented at this time as a substantial copy of *Tezuka*'s patent claim 1 in order to provoke an interference with Wilson. *Tezuka* argued that Wilson had not claimed the same or substantially the same subject matter as that claimed in the *Tezuka* patent within the time required by the statute. The Board held that Wilson had claimed substantially the same subject matter as that of *Tezuka*'s claims 1 to 3 prior to one year from the date on which the *Tezuka* patent was granted. The Board found that "the words 'prior to' in 35 U.S.C. § 135(b) point to a critical date prior to which the copier had to be claiming the invention. *It does not matter whether the claims are subsequently cancelled either before or after the issuance of the patent.*" (*id*, at 1036) *(emphasis added)*.

Like Wilson in the *Tezuka* case, the Applicant herein introduced the "conflicting claims" in the parent '836 application and subsequently cancelled them. In *Tezuka*, Wilson introduced the conflicting claims in an application that was filed one year after the issuance of the *Tezuka* patent. Likewise, the "conflicting claims" in the present '679 application were originally introduced in a parent application that was pending during the pendency of the Pfizer '317 patent.

Following the reasoning set forth in *Tezuka*, Applicant should be allowed to reintroduce the "conflicting claims" in the present divisional application and request an interference pursuant to 37 C.F.R.

§ 1.607, even though this divisional application was filed more than one year after the issuance of the Pfizer '317 patent.

Applicants are entitled to the benefit of all prior U.S. applications for proposed Counts 1 and 2, including Application No. 08/706,836, filed on September 3, 1996, which issued as U.S. Patent 6,326,383 B1 on December 4, 2001, which is a continuation of Application No. 08/579,294, filed on December 27, 1995, which issued as U.S. Patent 5,798,363 on August 25, 1998, which is a continuation of Application No. 08/269,079, filed June 30, 1994, which issued as U.S. Patent 5,538,982 on July 23, 1996, which is a divisional of Application No. 07/946,635, filed on September 18, 1992, which issued as U.S. Patent 5,360,820 on November 1, 1994.

Applicants are also entitled to the filing date of U.K. application 92 04151.6 for proposed Counts 1 and 2, which was filed on February 27, 1992. A copy of this application is attached hereto.

The Examiner is requested to refer in particular to the first full paragraph on page 14 of the U.K. application which reads as follows:

> The tachykinin antagonists may, if desired, be administered [in] combination with one or more other therapeutic agents and formulated for administration by any convenient route in a conventional manner. Appropriate doses will be readily appreciated by those skilled in the art. For example, the tachykinin antagonists may be administered in combination with a systemic anti-inflammatory corticosteroid such as methyl prednisolone or dexamethasone, or a $5HT_3$ antagonist such as ondansetron, granisetron or metoclopramide.

For the foregoing reasons, Applicant submits that all of the provisions of 37 C.F.R. § 1.607 have been met, and respectfully requests

that an interference be declared between the present '679 application and the Pfizer '317 patent.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number shown below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

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RCS/GMM/las/kdm

Attachments:
Marked-up Version Showing Changes Made
Appendix A
U.K. Application No. 92 04151.6

MARKED-UP VERSION SHOWING CHANGES MADE

In the Specification:

The first paragraph on page 1 of the specification has been amended as follows:

This application is a [☐ continuation ☒] divisional [☐ continuation-in-part] of [co-pending] Application No. 08/706,836, filed on September 3, 1996, which issued as U.S. Patent 6,326,383 B1 on December 4, 2001, which is a continuation of Application No. 08/579,294, filed on December 27, 1995, [now] which issued as U.S. Patent 5,798,363 on August 25, 1998, which is a continuation of Application No. 08/269,079, filed June 30, 1994, [now] which issued as U.S. Patent 5,538,982 on July 23, 1996; which is a divisional of Application No. 07/946,635, filed on September 18, 1992, [now] which issued as U.S. Patent 5,360,820 on November 1, 1994; the entire contents of which are hereby incorporated by reference and for which priority is claimed under 35 U.S.C. § 120; and this application claims priority of Application Nos. 91 20172.3; 92 02839.8; and 92 04151.6 filed in Great Britain on September 20, 1991; February 11, 1992; and February 27, 1992, respectively, under 35 U.S.C. § 119.--

Appendix A

Claims in Application No. 08/706,836 (Parent Appln.)	Claims in Application No. 09/986,679 (Present Appln.)	Disclosure in the '836 and '679 Applications which supports the corresponding claims.
18	1 (Proposed Count 1)	Page 1, lines 23-27; Page 2, lines 23-26; Page 22, lines 5-8; and Page 28, lines 18-25
20	3 (Proposed Count 2)	Page 22, lines 5-8; Page 28, lines 22-25